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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,892	05/29/2001	Stephen Christopher Porter	8600-0015	5581
7590 07/27/2004 ROBINS & PASTERNAK LLP 1731 EMBARCADERO ROAD STE 230 PALO ALTO, CA 94303			EXAMINER IZAGUIRRE, ISMAEL	
			ART UNIT 3765	PAPER NUMBER

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/866,892

Applicant(s)

PORTER, STEPHEN  
CHRISTOPHER

Examiner

Ismael Izaguirre

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,14,16,19-21,24,26-32,40,42 and 45-49 is/are rejected.
- 7) ☒ Claim(s) 7-13,15,17,18,22,23,25,33-39,41,43 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

The examiner is appreciative of the changes made to the language of the claims. These have been duly noted and considered.

### CLAIMS

#### Summary

Claims 1 and 27 are the independent claims under consideration in this Office action.

Claims 3-26 and 28-49 are the dependent claims under consideration in this Office action.

Concerning the Patentability of the claims, the following is submitted for applicant's consideration:

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-5,8-10,14,19-30,34-37, and 44-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,5,8,22,28-31,36, and 45 of copending Application No. 10/423,304.

Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1, 26-28, 47 and 48 of the instant application correspond to claims 1 and 29 of the '304 application since they essentially teach the use of a vaso-occlusive element formed from injection molded absorbable material or would have provided the understanding to do so to one of ordinary skill in the art. Further the remaining claims would have been obvious to one of ordinary skill in the art from the claims of the '304 application and the general knowledge in the art since all that is claimed is either taught in the claims or is suggested from the '304 claim language.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1,3-7, 11-32, 37-39, 41, 42, and 45-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7 12, 13, 18-20 and 22 of U.S. Patent No. 6,585,754 (Wallace et al. – commonly assigned to Scimed Life Systems, Inc.) in view of 6,332,884 (Cooper). Wallace teaches the invention with the exception of forming the vaso-occlusive device via injection molding. Cooper teaches that it is well known to provide surgical structural devices via multiple methods including extrusion and injection molding. Those devices include vascular implants and preformed defect fillers. Therefore it would have been obvious to one of ordinary skill in the art to have formed the device as taught by Wallace

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et al. through the method of injection molding since Cooper has indicated that along with extrusion molding the method of injection molding is a preferred means to form 3-dimensional articles of absorbable material.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 14, 16, 19-21, 24, 26-32, 40, 42, and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper (6,332,884) in view of Palermo (6,656,173).

Cooper discloses the invention substantially as claimed. Cooper teaches the use of biocompatible absorbable polymeric 3-dimensional injected molded medical devices (col. 4, lines 41-53). Some of these devices includes vascular implants and

preformed defect fillers (col. 6, lines 18 and 27). The material includes at least some of the preferred absorbable of the instant claims. Further Cooper teaches that it is known to mix additional elements into the matrix so as to use that material in the treatment of the individual (col.5, lines 4-7). Cooper fails to directly teach injection molding of a vaso-occlusive element having a particular configuration, the use of cutting or machining to assist in forming the device or the use of radio-opaque material in the device.

Palermo discloses that it is known to form a vaso-occlusive device by injection molding (col. 8, lines 29-34). It is also taught that a pusher device is employed using pressure to set the vascular device (see figs.)

It would have been obvious to one of ordinary skill in the art to have formed the absorbable injection molded device of Cooper into a 3-dimensional coil or other well know configuration used as a vaso-occlusive element as taught by Palermo since Palermo states that it is well known to form the vascular elements using injection molding. The formation of a vessel occlusion element would have been obvious since both Cooper and Palermo disclose the use of injection molding for use in a medical device and the only difference being material used would have allowed the ordinary skilled artisan to discover the use of all compatible materials for use in the process.

Since Palermo discloses use of a pusher and the disclosure of multiple types of occlusion devices it would have been obvious to have used the pusher and the various type of vascular devices in the teachings of Cooper. As far as the exact configuration of the vaso-occluder the examiner takes the position that since each are equivalent in the

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art the substitution of one for another would have been discovered through routine experimentation. As to claims 19-21 and 49, each of the methods defined in the claims are well known methods for shaping devices for use in the human body and would have been well known to the artisan of ordinary skill and, therefore, obvious. As to claims 24, 45 and 46, it is well known in the art to use radio-opaque material inside the human body so as to check through x-ray or other means the correct placement etc of a surgical device. Cooper teaches that it is well known to incorporate additional materials for certain uses within the matrix of absorbable polymers. Therefore, it would have been obvious to one of ordinary skill in the art to have incorporated a radio-opaque material such as those well known substances identified in the claims into the matrix so as to identify and correctly place the vascular device.

#### **ALLOWABLE SUBJECT MATTER**

Claims 7-13,15,17,18,22,23,25,33-39,41,43 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's arguments with respect to claims 1 and 2-49 have been considered but are moot in view of the new ground(s) of rejection.

#### **PERTINENT CITATIONS**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bezwada et al. Illustrate absorbable copolymers for use in surgical devices (col. 2, lines 59-67) by extrusion or injection molding (col. 7, lines 45-

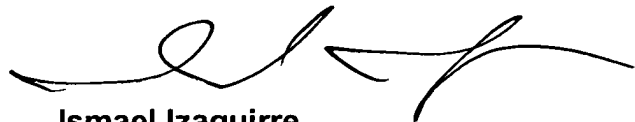
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50). Matsuda et al. Illustrate absorbable polymers used for forming screws, pins and staples by injection molding or extrusion. Cooper '596 illustrates biocompatible absorbable polymers for use as implantable devices formed of injection molding or extrusion (para. 22,23 and 48). Tormala et al. illustrate bioabsorbable polymers formed by injection molding (para 41). Shikinami et al. Illustrate biodegradable and bioabsorbable implant materials.

### INQUIRIES

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0861.

Any inquiry concerning this communication or earlier communications directed to the examiner should be directed to Mr. Ismael Izaguirre at (703) 308-0892 located in CP2-4B18, Monday through Friday 9:30am to 6:00pm.



**Ismael Izaguirre  
Primary Examiner  
Group Art Unit 3765**

II

7/25/04